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April 2019

Dear Principal Investigator:

RE: IRB Membership and Function

This information is being provided in response to requests from study sponsors for information about the membership and function of the Institutional Review Board (IRB) at the University of California, San Francisco (UCSF). The IRB is within the Human Research Protection Program (HRPP), along with the Quality Improvement Unit (QIU).

For sponsored studies, the IRB applies the FDA regulations found in 21 CFR parts 50 and 56 which includes, by guidance, the International Conference on Harmonization-Good Clinical Practice Guidelines (ICH-GCP) guidance (E6).

UCSF holds Federalwide Assurance (FWA) number 00000068. UCSF has four registered IRBs and meets the DHHS 45 CFR 46 Subpart E and FDA 21 CFR 56 regulation requirements for IRB registration.

Current IRB member rosters are available on the HRPP website. IRB members are assigned studies based on their expertise. If an IRB member has a conflict of interest, he or she will not participate in the deliberation and voting of that protocol. Please refer to the Investigator Conflict of Interest guidance on the HRPP website for additional information.

All IRB reviews are conducted on the IRB electronic submission system, IRIS, which is 21 CFR Part 11 compliant. Additional information can be found on the IRIS frequently asked questions (FAQ) website.

If you have any other questions about the Committee membership or function, please call the office at 415-476-1814 and ask to speak with the HRPP Director.

Thank you,

Laurie Herraiz, RD, CCRP, CIP
Director, Human Research Protection Program